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Benign Prostatic Hyperplasia (BPH): Medical and Hormonal Therapy
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The Impact of Medical Therapy on the Clinical Progression of BPH: Results of the MTOPS Trial. *The MTOPS Research Group, NIH-NIDDK, Bethesda, Maryland (presented by J McConnell)*

Background: The Medical Therapy of Prostatic Symptoms (MTOPS) Study, a multi-center clinical trial sponsored by the NIH, evaluated whether treatment with doxazosin and finasteride in combination was more effective than either drug alone in preventing the clinical progression of BPH.

Methods: 3,047 men randomized to doxazosin, finasteride, combination therapy, or placebo in a double-masked fashion had an average of 4.5 years of follow–up. The primary outcome was the time to clinical progression of BPH, defined as either a ≥4-point increase in AUA symptom score, acute urinary retention (AUR), incontinence, renal insufficiency or recurrent UTI. Secondary outcomes were changes in AUA symptom score and Qmax over time. Survival analysis and non–parametric data analysis techniques, respectively, were used to compare the treatment groups with respect to the primary and secondary outcomes. Treatment groups were also compared with respect to time to BPH invasive therapy (INVT) using survival analysis techniques.

Results: Combination drug treatment significantly reduced the incidence and delayed the clinical progression of BPH compared to each drug alone [Crude rate per 100 patient years (PYRs): Placebo=4.5, Doxazosin=2.7, Finasteride=2.9, Combination therapy=1.5; Risk reduction compared to placebo: Doxazosin=39%, Finasteride=34%, Combination therapy=67%]. Combination therapy and finasteride significantly reduced the risk of AUR [Crude Rate per 100 PYRs: Placebo=0.6, Doxazosin=0.4, Finasteride=0.2, Combination therapy=0.1] as well as the risk of INVT [Crude Rate per 100 PYRs: Placebo=1.3, Doxazosin=1.2, Finasteride=0.5, Combination therapy=0.4]. All treatments produced significant improvements in AUA SS [Median improvement at 4 years: Placebo=4.0, Doxazosin=6.0, Finasteride=5.0, Combination=7.0] and Qmax [Median improvement (ml/sec) at 4 years: Placebo=1.4, Doxazosin=2.5, Finasteride=2.2, Combination=3.7]. Improvements in AUA SS and Qmax in the combination therapy were significantly greater compared to doxazosin or finasteride therapy alone. Frequently occurring adverse events were similar to previously reported trials. Men in the placebo group with higher baseline serum PSAs, prostate volumes, and ages, and lower Qmax were significantly more likely to progress.

Conclusions: The combination of doxazosin and finasteride significantly delayed the clinical progression of BPH as compared with each drug individually among men with symptomatic BPH. Combination therapy was more effective than doxazosin or finasteride alone in producing significant improvements in AUA SS and Qmax.